PCT/GB 2003 / 0 0 2 9 6 1

INVESTOR IN PEOPLE

The Patent Office
Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

PRIORITY DOCUMENT

SUBMITTED OR TRANSMITTED IN COMPLIANCE WITH RULE 17.1(a) OR (b)

REC'D 13 NOV 2003
WIPO PCT

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

I also certify that the application is now proceeding in the name as identified herein.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

In accordance with the rules, the words "public limited company" may be replaced by p.l.c., plc, P.L.C. or PLC.

Re-registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.

Signed R Mahoney

Dated 4 November 2003

INVESTOR IN PEOPLE

GB0215904.4

By virtue of a direction given under Section 30 of the Patents Act 1977, the application is proceeding in the name of

OPTINOSE AS,
Lokkaskogen 18c,
0773 Oslo,
Norway

Incorporated in Norway,

[ADP No. 08042905001]

Patents Form 1/77

Patents Act 1977
(Rule 16)

THE PATENT OFFICE
A
- 9 JUL 2002
RECEIVED BY FAX

The Patent Office

1/77

Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form.)

09 JUL 2002

0215904.4

Fee: £0 - (£25 Faxback)

The Patent Office
Cardiff Road
Newport
Gwent NP9 1RH

1. Your reference: SJNG/44854.GB01

2. Patent application number *(The Patent Office will fill in this part)*: 10JUL02 E732111-1 D01631 P01/7700 0.00-0215904.4

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*:
Team Holdings (UK) Limited
Cokenach
Barkway
Hertfordshire
SG8 8DL

08033557001
Patents ADP number *(if you know it)*

If the applicant is a corporate body, give the country/state of incorporation: United Kingdom

SECTION 20 (1977 ACT) APPLICATION FILED 10/7/02

4. Title of the invention: Drug Delivery System and Method

5. Full name, address and postcode in the United Kingdom to which all correspondence relating to this form and translation should be sent:
Reddie & Grose
16 Theobalds Road
LONDON
WC1X 8PL

Fry Heath & Spence LLP
The Gables
Massetts Road
Horley, Surrey
RH6 7DQ

91001
052 80073001

Patents ADP number *(if you know it)*

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application *(if you know it)*	Date of filing *(day/month/year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day/month/year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*
a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d))

YES

Patents Form 1/77

0041227 09-JUL-02 05:36

Patents Form 1/77

Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document.

Continuation sheets of this form	
Description	2
Claim(s)	
Abstract	ONE
Drawing(s)	3 ONLY

10. If you are also filing any of the following, state how many against each item.

Priority documents	
Translations of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination and search *(Patents Form 9/77)*	
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature Reddie & Grose REDDIE & GROSE

Date 9 July 2002

12. Name and daytime telephone number of person to contact in the United Kingdom

S J N GOODMAN
01223 360350

Warning

After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or such direction has been revoked.

Notes

a) *If you need help to fill in this form or you have any questions, please contact the Patent Office on 0645 500505.*

b) *Write your answers in capital letters using black ink or you may type them.*

c) *If there is not enough space for all the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.*

d) *If you have answered 'Yes' Patents Form 7/77 will need to be filed.*

e) *Once you have filled in the form you must remember to sign and date it.*

f) *For details of the fee and ways to pay please contact the Patent Office.*

Drug Delivery System and Method

The invention relates to a single shot disposable nasal insuflator based on innovative packaging technology.

Background

The nasal delivery for a range of powder and liquid drugs has been established for some time and there are a range of existing products on the market which use this method. The oral route for drug delivery is far more prevalent, but there is an increasing amount of research being carried out in the nasal delivery technologies.

'Form, fill and seal' packaging using vacuum forming/laminating and aluminium foil technologies is well established for a range of product types, both in the pharmaceutical sector (including capsule blister packs and sachets for lyophilised drugs) and for a large range of other types of product (e.g. coffee sachets and adhesives). Two compartment pouches with breakable barrier seals between the compartments are well established technologies. Also, in many cases and especially non-pharma applications, 'form fill and seal' plastic products incorporating welded-in injection moulded spouts and caps are commonplace.

Summary of the invention

The technology on which protection is sought is the use of a breakable seal in a 'form fill and seal' pouch as the basis of a single use product that will allow the generation of a cloud of powder particles or liquid droplets. A pouch containing liquid or powder would be sealed such that, on the direct or indirect application of pressure, a specific barrier seal will burst such that the now pressurised liquid/powder is expelled through an attached spout or nozzle. The key to the invention is the ability to 'tune' the pressure at which the barrier seal is broken, and to control the characteristics of the subsequent flow of liquid/powder.

In a second aspect, the liquid or powder may be contained in the nozzle prior to delivery, separated from the pouch by the breakable barrier seal. Compression of the pouch increases the pressure therein, which causes the seal to break and delivers the liquid or powder through the nozzle.

Preferably, the pouch may be constructed so that it collapses only when a predetermined external force is applied to it, for example by a user's hand. The pouch may then collapse in a rapid, predetermined way. This may advantageously make the seal break in a more predictable manner.

Advantageously, the interior of the pouch may carry a spike or blade positioned so as to penetrate the seal, or assist rupturing of the seal, when the pouch is compressed, preferably to a predetermined volume. This may rupture the seal at an advantageously predictable pouch pressure.

In the specific applications described, the invention enables the manufacture of a low cost disposable drug delivery device based on manufacturing processes that are, separately, already well established.

Figure 1 shows isometric views of a first embodiment of the invention before and after compression of the pouch.

Figure 2 shows isometric and sectional views of a second embodiment of the invention.

Specific description

In a first embodiment, the invention provides a single shot disposable nasal insuflator drug delivery device (figure 1). This is a foil/vacuum formed 'form, fill and seal' approach whereby failure of a barrier seal requires a certain amount of force to be applied to a pouch which, when released, acts as the motive force driving the dose out through the nozzle. In this case the drug within the pouch could be in powdered form, and the spout/nozzle would be of a design appropriate for the delivery of the drug to the target site. In conjunction with a barrier seal which failed at the required pressure, the nozzle would deliver a dose of powdered drug in to the nasal cavity. Powder particle size would be largely determined by the processing methods but would need to be disagglommerated as required to give the necessary fine particle fraction. In a variation of this embodiment the drug is housed within the nozzle rather than in the pouch prior to delivery.

In a second embodiment, the invention utilises an essentially hemispherical or similar dome form such that, in addition to having a barrier which breaks at a given pressure, the force displacement characteristic of the dome could be tuned to give suddenly at an applied force threshold. The rupturing of the barrier seal could be effected purely by the pressure generated, or by some other mechanism (e.g. a puncturing spike on the inner face of the dome as shown in Figure 2), or both. Figure 2 illustrates a collapsing dome whereby a force is applied to the dome which collapses at a certain threshold. The sudden release causes a 'spike' feature on the underside of the dome to cause or help cause the bursting of the barrier seal, resulting in the dose being expelled through the nozzle.

Alternative implementations of the technology could use variations in the nature of the product contained within the pouch, e.g. liquids of differing densities and viscosities as opposed to powder, with the nozzle geometry and force profile combining to generate a liquid aerosol of liquid droplets that gave optimum effectiveness of drug delivery.

There could also be variations in barrier seal burst pressures, and variations in nozzle types and geometries, to produce a drug delivery device with a range of applications.

The same technology could be used for a range of non-healthcare applications where a one-off controlled release of powder or liquid is required.

1/3

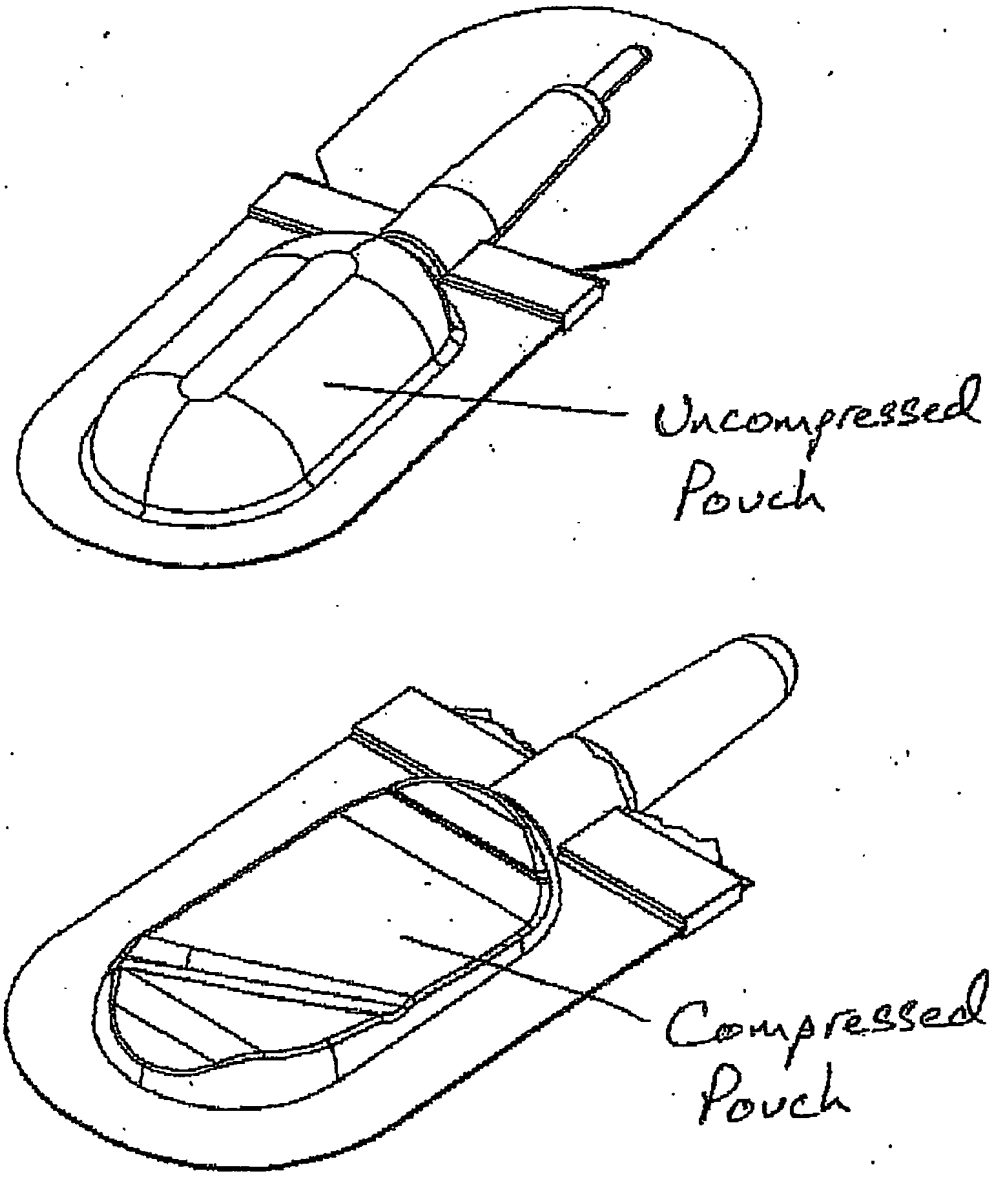

Figure 1

2/3

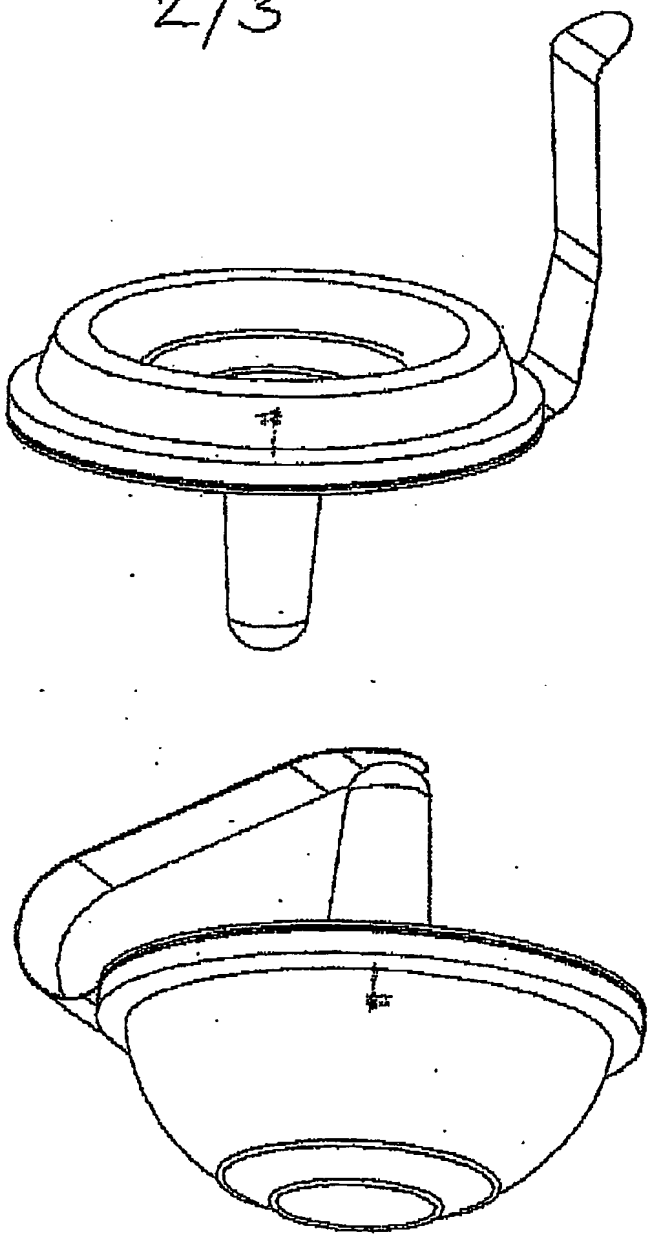

Figure 2A

3/3

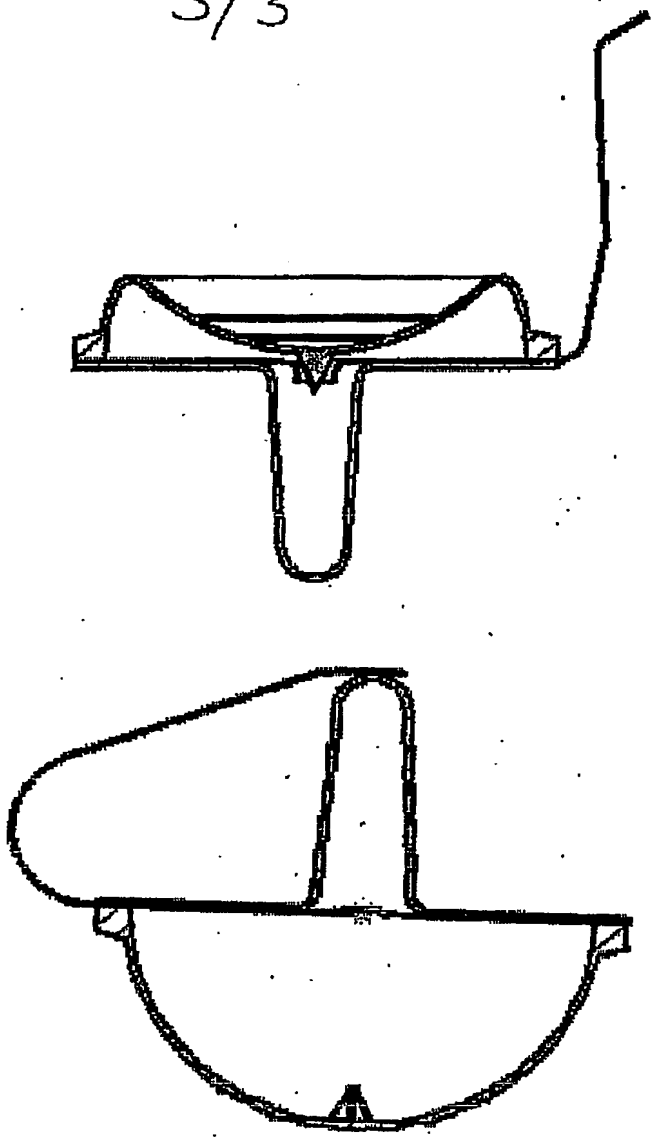

Figure 2b